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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/722,620	11/26/2003	Richard J. Melker	10457-125C	7104
29847 7590 09/04/2008 Beusse Wolter Sanks Mora & Mairc 390 N. ORANGE AVENUE SUITE 2500 ORLANDO, FL 32801				
EXAMINER TURK, NEIL N				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/722,620

Applicant(s)

MELKER ET AL.

Examiner

NEIL TURK

Art Unit

1797

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 6/3/08.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 4-27 and 29-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4-27 and 29-34 is/are rejected.
- 7) ☒ Claim(s) 12-15 and 31 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Remarks

This Office Action fully acknowledges Applicant's remarks filed on June 3rd, 2008. Claims 1, 2, 4-27, and 29-34 are pending. Claims 3 and 28 have been cancelled. Claims 31-34 are newly added. Any objection/rejection not repeated herein has been withdrawn by The Office.

Claim Objections

Claim 12-15, and 31 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 12-15 and 31 recite limitations to where the marker is included. Claims 12-15 and 31 do not further limit the method of claim 1 as the limitations in claims 12-15 and 31 do not establish a further step to the method or define a more specific step to the method already described in claim 1. Examiner asserts that the recitations of claims 12-15 and 31 appear to be intended to further limit the "providing" step of claim 1, and should be amended accordingly to recite positive steps of the various means of providing so as to further limit claim 1.

Claim 31 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 9. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 4-27, 29, and 30 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for providing a medication that itself comprises the marker, does not reasonably provide enablement for providing a combination of a medication and an marker so as to detect the present/absence of the odorous marker to indicate compliance/non-compliance in taking the medication. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make/use the invention commensurate in scope with these claims. Applicant's method is directed toward detecting the presence of a marker in a patient's breath in order to assess compliance/non-compliance in taking medication. Thereby, the marker must be a part of the medication, otherwise no positive connection with the marker can be made to the medication. The currently recited method is not operable in detecting if the medication has/has not been taken as

it only tests if the marker has/has not been taken. By this, the Examiner asserts that the recitation to a "combination of a medication and a marker" may point to providing a patient with two separate items, of both a medication and a marker. Thereby, as discussed above, detection (or lack of) of the marker will not have correlation with the medication being taken or not taken.

Claim 32 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification does not disclose that the marker is a combination of markers combined as an additive with the medication. In paragraph [0044] of Applicant's pre-grant publication US 2004/0081587, Applicant discloses, in relevant part, "...Furthermore, combinations of marker substances could be used allowing a rather small number of markers to specifically identify a large number of medications." However, this disclosure does not relate to a combinations of markers combined as an additive, and thereby the recitation of claim 32 is seen as new matter.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2, 4-27, and 29-34 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted

elements are: that the medication includes the marker. As discussed above with respect to the rejection of the claims under 112, 1st paragraph, the marker must be included with the medication in order for the method to be operable for its purpose. Otherwise, there is no connection established to the presence/absence of the marker and the medication being taken. Examiner notes that claims 2, 9, and 10 have such limitations.

Claims 23-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The further defined method step in claims 23-25 is unclear as the language does not positively and actively set forth the method step that is undergone in each respective claim. For example, Examiner asserts that claim 23 should be written as an active method step, such as, "The method of claim 1, further comprising reacting the marker with enzymes in the patient's mouth". The same such language should be applied to claims 24&25 so as to recite active and further method steps to claim 1.

Claims 29 and 30 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: how the medication combined with the detectable marker is produced. Claim 29 recites steps of identifying a marker substance detectable in gaseous breath and then producing a medication with

said detectable marker substance. Applicant has not provided specific manufacturing steps for producing the combination of the medicine and the marker so as to be detectable and act as an indication of patient compliance. As such, a general statement in the prior art of producing a medication combined with a detectable marker will be read to constitute any production step(s) (or if the final product is a medicine with a detectable marker, in which the production is inherent to arrive at the final product) which results in a medicine with a detectable marker. Further, claim 30 does not further limit the method of producing the medication with further steps that provide for it being a transdermally delivered medication, and thus such limitations are not afforded any patentable weight. Claim 30's recitation is drawn to an intended use.

Claim 33 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear what is meant by the recitation that more than one medication is included in the medication. Applicant's inventive method of claim 1 is drawn to checking patient compliance in taking a medication. Thereby, it is unclear how Applicant's method is operable if more than one medication is being taken. Does Applicant intend to recite that there are more than one active ingredient within the medication that is being taken? This recitation is unclear and requires appropriate correction to coincide with the method of claim 1. As currently recited, prior art which discloses a medication with more than one active ingredient will be taken to read on the recitation of claim 33.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 7-21, 23-27, 29-31, 33, and 34 are rejected under 35 U.S.C. 102(e) as being anticipated by Katzman (5,962,335).

Katzman discloses a breath test for detection of drug metabolism (abstract; columns 1&2). Katzman discloses that a safe and effective amount of the drug, isotopically-labelled (additive to the drug; also considered a coating as it is applied on the drug) is administered to a subject. Katzman discloses a breath test kit in which after a suitable amount of time the exhaled breath of the subject is analyzed to determine the concentration of a metabolite (marker, with use of the isotope), which is then used to determine the rate of metabolism of the drug (abstract; lines 30-33). Katzman also discloses that the exhaled breath of the subject is analyzed before the drug is administered so as to give a baseline for the concentration of the metabolite in the breath of the subject (lines 50-67, col. 5). Katzman also discloses that the label used to identify the metabolite in the exhaled breath of the subject should at least be present on a portion of the drug that forms the metabolite (columns 7 and 8; lines 22-26, col. 6).

Katzman discloses that administrations include such things as powders or granules, suspensions or solutions in water, capsules and tablets and flavorings (stimulating salivation). Examiner asserts that such flavorings would act as odorous markers whose presence or absence could be analyzed qualitatively as an indication of compliance or noncompliance in taking the drug. Katzman also discloses that the drug may be administered topically, such as intranasally, or parenterally such as by intravenous drip or intraperitoneal, subcutaneous, or intramuscular injection, or administration may be done by inhalation (lines 43-67, col. 6). Katzman discloses that following the step of administering the drug to the subject, the exhaled breath of the subject is analyzed to detect a metabolite or metabolites, and subsequently the concentration of the metabolite is used to determine the rate of metabolism of the drug (lines 13-36, col. 7; col. 14). Katzman discloses that the metabolite or metabolites are detected by an instrument such as a gas analyzer, mass spectrometer, or infrared spectrometer (lines 21-36, col. 7; lines 38-40, col. 8). Katzman also discloses that the breath test could be used for therapeutic drug monitoring in determining the concentration of the metabolite(s) in the exhaled breath of the subject and using such information to properly adjust the dosing regimen for the subject (lines 58-67, col. 9; lines 1-2, col. 10). Examiner asserts that the acquisition of the two concentration measurements necessary for employing the difference between them to establish an acceptable dosage regimen would inherently constitute recording the two concentration measurements at their respective measurement steps.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Katzman in view of Payne (WO 98/39470).

Katzman has been discussed above.

Katzman does not specifically disclose analyzing the patient's breath to confirm the presence of the marker by either semiconductor gas sensor technology or conductive polymer gas sensor technology.

Payne discloses a method of detecting conditions by analysis of gases or vapors. Payne discloses that the gas sensing device may comprise an array of semiconducting organic polymer gas sensors and the presence of any species present in the gas phase may be detected (pages 1-3). Payne discloses that other types of gas sensors such as metal oxide semiconductor (MOS), quartz resonator or SAW devices, as well as mass spectrometry or a GC-MS device might be used (pages 3-5). Payne discloses that an array of such sensors are used so as to permit selective identification of a wide range of gases by recognizing the characteristic "fingerprint" of response across the array. Payne discloses that the output of the sensors correlates the output pattern (analyzed by analysis means 22) with the occurrence of certain conditions (page 4). Payne also discloses that it is possible to reduce water content by using purge and trap systems (page 6).

It would have been obvious to modify Katzman to test the breath sample with semiconducting gas sensors such as taught by Payne in order to provide dynamic sensing technology for gases or vapors that may produce a characteristic response to

correlate a condition such as to show the presence or absence of the flavoring ingredient in the patient's breath.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Katzman in view of Forester (4,762,719).

Katzman has been discussed above.

Katzman does not specifically disclose a marker as listed in claim 6.

Forester discloses a cough drop comprising a hard candy outer shell and a powdered centerfill containing a rapidly-dissolving powder and an active ingredient such as menthol and eucalyptus which is in the form of a liquid blend and a spray-dried powder. Forester discloses that the hard candy outer shell also contains menthol and eucalyptus as a liquid blend (abstract). Forester discloses that the rapidly-dissolving powders used enhance active ingredient release to provide the aromatic vaporization of the ingredient into the oral and nasal cavities (lines 50-68, col. 1; column 3 and Example 3). Forester also discloses that the flavors which may be employed in the hard candy shell include both natural and synthetic flavors such as citrus oils of cherry, lemon, orange, and lime, or essential oils such as peppermint, spearmint, or wintergreen, and also synthetic flavors (lines 48-55, col. 2).

It would have been obvious to modify Katzman to include citrus or menthol such as taught by Forester such that Katzman discloses that flavorings may be desirable, and it would be obvious to modify Katzman to include citrus or menthol for the purpose of making the drug/medication more amenable and comfortable to be taken orally, as

well as providing a marker that provides a qualitative assessment of compliance based on the odorous presence or lack thereof.

Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Katzman in view of Payne and in view of Ueda (5,425,374).

Katzman and Payne have been discussed above.

Katzman and Payne do not disclose dehumidifying the sample of the patient's breath prior to analysis.

Ueda discloses a method and device for expiratory air examination. Ueda teaches that an absorbing filter is provided for removing particulates and contaminants which would hinder the aimed examination. Ueda also discloses that a dehumidifying agent may be included partially in the absorbing filter (lines 11-62, col. 6).

It would have been obvious to modify Katzman to include dehumidifying the air sample with a dehumidifying agent before analysis such as taught by Ueda so as to remove any moisture that may hinder the aimed examination and further given that Payne discloses a similar breath sampling method and device in which Payne teaches possibly including filters or reducing water content.

Response to Arguments

Applicant's arguments filed June 3rd, 2008 have been fully considered but they are not persuasive.

With regards to claims 1, 2, 4-27, 29, and 30 rejected under 35 USC 112, 1st paragraph, under a scope of enablement issue, Applicant traverses the rejection. As discussed above, Examiner asserts that the problem in the claim language lies within the term “combination”. By this, the Examiner asserts that the recitation to a “combination of a medication and a marker” may point to providing a patient with two separate items, of both a medication and a marker. Thereby, as discussed above, detection (or lack of) of the marker will not have correlation with the medication being taken or not taken. Additionally, newly added claims 31-34 have been added to the rejection based on their dependency to independent claim 1.

With regards to claims 1, 2, 4-27, 29, and 30 rejected under 35 USC 112, 2nd paragraph, as omitting essential elements, Applicant traverses the rejection. Examiner asserts that, as discussed above within the 35 USC 112, 2nd paragraph section of the Office Action, and as discussed directly above with respect to arguments made over the rejection of the claims under 35 USC 112, 1st paragraph, the same issue remains and is maintained by the Examiner.

With regards to claims 23-25 rejected under 35 USC 112, 2nd paragraph, Applicant traverses the rejection. Applicant argues that claims 23-25, as herein amended, remove the indefiniteness previously cited. Examiner asserts, that as discussed above, the claims as herein amended, are maintained rejected based on the further interpretation and new grounds of rejection as discussed above.

With regards to claims 29 and 30 rejected under 35 USC 112, 2nd paragraph, Applicant traverses the rejection. Applicant has not provided specific manufacturing steps for producing the combination of the medicine and the marker so as to be detectable and act as an indication of patient compliance. As such, a general statement in the prior art of producing a medication combined with a marker will be read to constitute any production step(s) (or if the final product is a medicine with a detectable marker, in which the production is inherent to arrive at the final product) which results in a medicine with a detectable marker. Further, claim 30 does not further limit the method of producing the medication with further steps that provide for it being a transdermally delivered medication, and thus such limitations are not afforded any patentable weight. Claim 30's recitation is drawn to an intended use.

With regards to claims 1, 2, 7-9, 12-21, 23-27, 29, and 30 rejected under 35 USC 102(e) as being anticipated by Katzman (5,962,335), Applicant traverses the rejection.

Examiner asserts that Applicant's recitation to "providing" reads on the recitation in Katzman to "administering", and further, in both cases, as in Applicant's method and Katzman, there is a presumption that the drug/medication is to be taken. Examiner asserts that Applicant's method is not drawn to a random sampling of people, but is drawn to checking patient compliance in taking medication that has been provided or administered to the patient. Examiner further points to claim 1 of Applicant's method

which recites such a providing step and in further dependent claims, such as 14 and 15 the medication is provided intranasally and intravenously, further pointing to the fact that the "administering" in Katzman reads equivalently in breadth to the "providing" in Applicant's claims.

Applicant further argues that Katzman does not disclose the use of an additive to the medication to be detected. Examiner asserts that isotopically-labelling the drug constitutes such an additive to the medication for detection as the isotope is added to the drug to alter its original and base form.

Newly added claims 31, 32, and 34 are rejected as discussed above over Katzman under 35 USC 102(e).

With regards to claims 4 and 5 rejected under 35 USC 103(a) over Katzman in view of Payne, Applicant traverses the rejection. Applicant presents the same arguments over Katzman as earlier applied with respect to the claim rejections under 35 USC 102(e) with Katzman. As discussed above, no such deficiency exists in Katzman, and thereby the combination of Katzman in view of Payne is maintained as proper.

With regard to claim 6 rejected under 35 USC 103(a) over Katzman in view of Forester, Applicant traverses the rejection. Applicant generally asserts that it is unlikely that one skilled in the art would have any reason to combine these references in the absence of Applicant's teachings. Applicant further argues, as discussed above with respect to the claims being rejected under 35 USC 102(e) over Katzman, that Katzman

has deficiencies, and such deficiencies are not cured by Forester. Examiner argues that Forester discloses citrus, or menthol for example and Katzman has disclosure to the usage of flavorings, and thereby it would be obvious to include specific flavorings of citrus or menthol as known flavorings for the purpose of making the drug more amenable and comfortable to be taken orally. Further, as discussed above, Katzman does not have deficiencies with respect to independent claim 1, and thereby claim 6 is maintained rejected over Katzman in view of Forester.

With regard to claim 22 rejected under 35 USC 103(a) over Katzman in view of Payne and Ueda, Applicant traverses the rejection. Applicant argues that Ueda does not cure the defect in Katzman as previously argued above with respect to claim 1 and the rejection of the claims under 35 USC 102(e). Examiner asserts that as discussed above, there is no deficiency in Katzman and thereby the combination of Katzman in view of Payne and Ueda is maintained as proper.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NEIL TURK whose telephone number is (571)272-8914. The examiner can normally be reached on M-F, 9-630.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NT

/Jill Warden/
Supervisory Patent Examiner, Art Unit 1797